TAVI in severe AS patients with poor renal function

Myeong-Ki Hong, MD. PhD

Professor of Medicine

Cardiology Division, Severance Cardiovascular Hospital Yonsei University College of Medicine, Seoul, Korea



Declaration of Interest

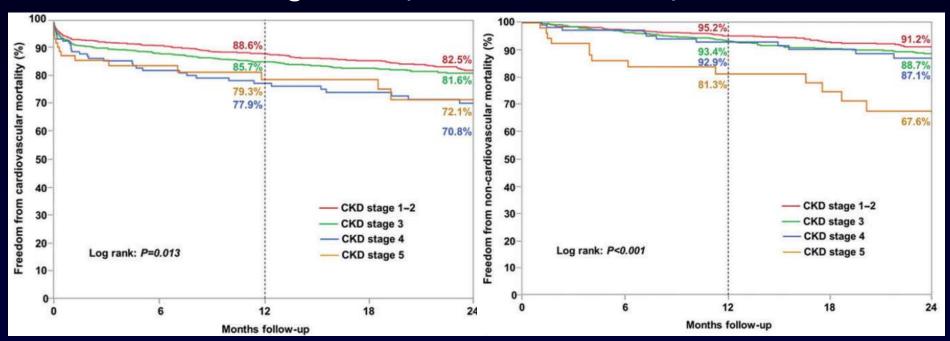
Proctor, Medtronic Evolut R



Clinical impact of CKD in patients with TAVI

Among 2,075 patients undergoing TAVI in Canada (During 2005-2012)

Prevalence of CKD grade ≥3 (eGFR <60 mL/min/1.73 m²) = 54%



Advanced CKD in patients undergoing TAVI seems to determine a higher risk for early and mid-term cardiovascular and non-cardiovascular mortality

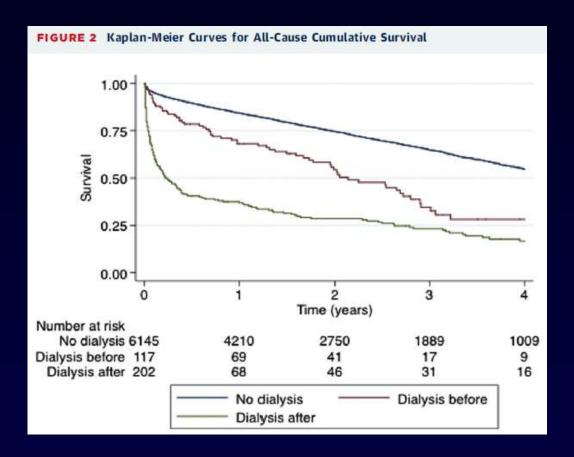
Allende R et al, EHJ 2014



Starting dialysis after TAVI

Among 6,464 patients undergoing TAVI in UK (During 2007-2014)

Incidence of dialysis after TAVI / before TAVI = 3.1% / 1.8%



Charles J. Ferro et al, J Am Coll Cardiol Intv 2017



Stages of AKI: VARC-2

Abrupt decrease in renal function within 7days

Stage 1

Increase in serum creatinine to 150-199% ($1.5-1.99 \times$ increase compared with baseline) OR increase of ≥ 0.3 mg/dL (≥ 26.4 mmol/L) OR Urine output < 0.5 mL/kg/h for > 6 but < 12 h

Stage 2

Increase in serum creatinine to 200-299% ($2.0-2.99 \times$ increase compared with baseline) OR Urine output <0.5 mL/kg/h for >12 but <24 h

Stage 3^b

Increase in serum creatinine to $\geq 300\%$ ($>3 \times$ increase compared with baseline) OR serum creatinine of ≥ 4.0 mg/dL (≥ 354 mmol/L) with an acute increase of at least 0.5 mg/dL (44 mmol/L) OR Urine output <0.3 ml/kg/h for ≥ 24 h OR Anuria for ≥ 12 h

The increase in Cr must occur within 48 h.

The timing for the diagnosis of AKI is extended from 72 h (VARC) to 7 days (VARC 2).

Eur Heart J 2012;33:2403



Meta-analysis of AKI and mortality after TAVI

Among 5,971 patients in 24 clinical trials

Incidence of Postoperative AKI after TAVI = 22%

	Early all-cause mortality								1-year all-cause mortality							
and the contract of the contra	AKI		No A	The state of the state of		Odds Ratio	Odds Ratio		AKI		No Al	KI		Odds Ratio	Odds Ratio	
Study or Subgroup	Events		Events	Total		CIT TO STATE OF THE PARTY OF TH	M-H, Random, 95% CI	Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95	% CI
Aregger et al	2	15	0	39	0.6%	14.63 [0.66, 324.29]	•	Barbanti et al		231	93	926	14.5%	3.00 [2.08, 4.33]	1,707, 314, 134, 134, 13, 10, 114, 14, 14, 14	79.44
Sagur et al	7	25	14	188	5.2%	4.83 [1.73, 13.52]			58		14.14					
Barbanti et al	21	231	24	926	15.7%	4.16 [2.30, 7.51]	-	Gebauer et al	12	28	20	112	7.1%	3.45 [1.42, 8.41]		
Barbash et al	7	24	10	141	4.6%	5.39 [1.81, 16.04]		Généreux et al	10	18	32	200	6.1%	6.56 [2.41, 17.90]		
Elhmidi et al	7	46	15	188	5.9%	2.07 [0.79, 5.42]	-	Johansson et al	6	21	- 8	43	4.6%	1.75 [0.52, 5.92]		
Garcia-Lara et al	3	17	1	114	1.0%	24.21 [2.36, 248.95]		Khawaja et al	28	89	24	159	10.3%	2.58 [1.38, 4.82]		
Gebauer et al	8	28	8	112	4.6%	5.20 [1.75, 15.48]	-	Kong et al	4	15	1	37	1.6%	13.09 [1.32, 129.66]	_	\rightarrow
Goebel et al		41	1.3	214	6.0%	3.75 [1.44, 9.74]		Konigstein et al	9	35	20	163	7.1%	2.48 [1.02, 6.03]		
Généreux et al	8	18	6	200	3.6%	25.87 [7.53, 88.91]		Nuis et al (2011)	12	22	21	96	6.4%	4.29 [1.63, 11.29]	-	_
Johansson et al	1	21	0	43	0.5%	6.37 [0.25, 163.10]		Nuis et al (2012)	59	206	140	789	14.7%	1.86 [1.31, 2.65]	-	
Keles et al	2	5	3.	65	1.2%	13.78 [1.63, 116.12]		Sala et al		42	2	60	4.6%	1.02 [0.30, 3.47]		
Khawaja et al	12	89	6	159	5.3%	3.97 [1.44, 10.99]		the state of the s	12	20		57	4.9%			
Kong et al	2	15	0	37	0.6%	13.89 [0.63, 308.13]	+	Sinning et al (2010)						9.19 [2.86, 29.48]		-00
Konigstein et al	4	42	2	209	1.8%	10.89 [1.93, 61.59]	-	Sinning et al (2014)	17	30	19	102	7.2%	5.71 [2.38, 13.74]		
Nuis et al (2011)	- 5	22	4	96	2.7%	6.76 [1.65, 27.79]	-	Yamamoto et al	30	63	55	352	11.1%	4.91 [2.77, 8.70]	-	-
Nuis et al (2012)	30	206	28	789	18.8%	4.63 [2.70, 7.95]										
Saia et al	3	42	2	60	1.6%	2.23 [0.36, 13.97]		Total (95% CI)		820		3096	100.0%	3.27 [2.42, 4.42]		
Sinning et al (2010)	5	20	4	57	2.7%	4.42 [1.05, 18.54]	-	Total events	262		448					
Sinning et al (2014)	5	30	1	102	1.1%	20.20 [2.26, 180.71]		Heterogeneity: Tau ¹ =	0.13: Ch	i' = 24	.10. df =	12 (P	= 0.02):	$t^2 = 50\%$	bar di	
Strauch et al	4	16	1	12	1.0%	3.67 [0.35, 38.03]		Test for overall effect						1000	0.01 0.1 1	10 100
Van Linden et al.	11	42	12	219	6.8%	6.12 [2.49, 15.07]	-	Contract System street	Mr. Tr. P. College	100	CO-D-G-G-G-G-G-G-G-G-G-G-G-G-G-G-G-G-G-G-				Worse No AKI Worse	AKI
Wessely et al	5	49	1	134	1.2%	15.11 [1.72, 132.89]									The state of the s	
Yamamoto et al	10	63	14	352	7.4%	4.56 [1.92, 10.78]										
Total (95% CI) Total events	172	1107	169	4456	100.0%	5.09 [4.03, 6.43]	•									

Risk of AKI for early all-cause mortality = OR 5.09 (4.03-6.43) Risk of AKI for 1-year all-cause mortality = OR 3.27 (2.42-4.42)

Gargiulo G et al.CCI 2015



Pathomechanisms of AKI during TAVI

- Contrast agent
- Concomitant drugs
- Blood loss
- Rapid pacing with resulting hypotension and renal hypoperfusion
- Embolization during the implantation due to patient's age and frequent coexistence of atherosclerosis,
- Postoperative severe inflammatory response syndrome



Contrast volume and AKI in TAVI procedure

Among 270 patients undergoing TA-TAVI in Germany (During 2006-2009)

Table 6. Significant risk factors for	postoperative AKI after	TA-AVI in univariate and multivariate analysis.
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	Odds ratio (95% CI)	p-value
Univariate		1 1 1
Procedure time > median (75 min)	2.1 (1.1-4.1)	0.034
Need for cardiopulmonary bypass	2.8 (1.1-7.0)	0.028
Intra-operative conversion to sternotomy	16.8 (1.7-165.4)	0.016
Contrast-agent burden > median (90 ml)	2.6 (1.3-5.2)	0.007
Contrast-agent burden > median (1.37 ml kg ⁻¹ body weight)	3.0 (1.4-6.1)	0.003
Number of blood transfusions > 4 ^a	3.7 (1.7-7.9)	0.001
New thrombocytopenia for more than 2 days a	7.6 (3.3-17.2)	< 0.001
Leucocyte count > 12 G/l for more than 2 days a	3.6 (1.8-7.1)	< 0.001
Multivariate	THE POSSESSE TO SERVICE STOPPENESSES	ROScore mercence
Contrast-agent burden > median (90 ml)	2.3 (1.0-4.9)	0.038
Contrast-agent burden > median (1.37 ml kg ⁻¹ body weight)	2.5 (1.1-5.4)	0.023
New thrombocytopenia for more than 2 days*	4.4 (1.6-12.2)	0.005
Leucocyte count > 12 G/l for more than 2 days a	2.8 (1.3-6.0)	0.009

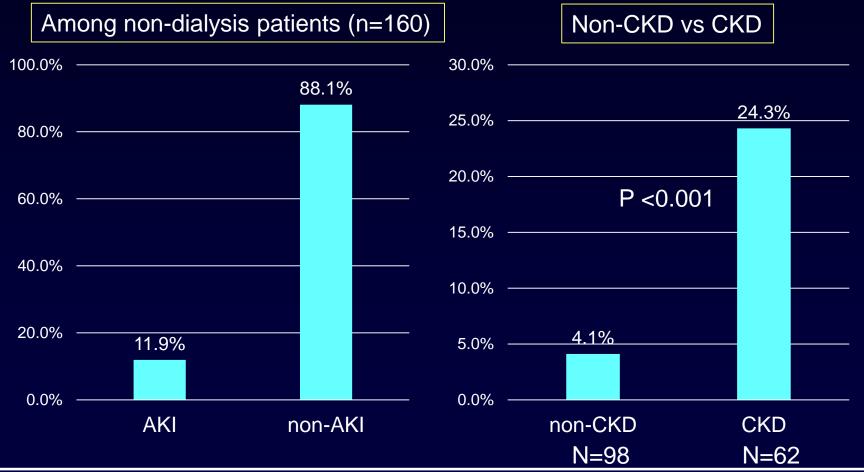
"Postoperative AKI and RRT depend on the amount of intra-operative contrast agent. These results strongly support the need for intra-operative tools to reduce contrast-agent exposition during TA-AVI."

Van Linden A et al, European Journal of Cardio-Thoracic Surgery 2011



Severance Hospital: Incidence of AKI after TAVI

- From July 2011 to April 2018, 180 TAVI patients (mean age 81.6 years old)
- CKD stage 3~5 (GFR<60 mL/min): 45.6%





Zero-Contrast TAVR for Severe AS in Patient with CKD

Operator: Myeong-Ki Hong, Young-Guk Ko, Jung-Min Ahn

An 88-year-old female was admitted due to dyspnea (NYHA functional class III). She had a history of hypertension, diabetes, stage 4 chronic kidney disease (CKD), and persistent atrial fibrillation. Coronary angiography showed no significant stenotic lesion. Echocardiography showed normal left ventricular ejection fraction but severe aortic stenosis was noted (Figure 1). Aortic valve area was 0.96 cm2 on the planimetry method. Peak velocity across aortic valve was 4.2 m/s, and mean pressure gradient was 30 mmHg. STS score was 8%.

Because of CKD, CT angiography was not done. From the 3D echocardiographic data, the mean annulus diameter was 24.6 mm and the perimeter was 71.2 mm. Distance from annulus to LM and RCA ostium was 16.3 and 15.8 mm, respectively. Because of stage IV CKD, TAVR was planned without using contrast agent.

Under general anesthesia, temporary pacemaker was inserted through right femoral vein. 7 Fr sheath and 6 Fr pigtail catheter were inserted through right femoral artery under sono-guided puncture technique. 8 Fr sheath was inserted through left femoral artery and replaced with 18 Fr Figure 1 Sentrant sheath. Straight coil

wire under back-up with an AL 1 diagnostic catheter was crossed the stenotic aortic valve. Then, straight coil wire was changed to the round-shaped Amplatz stiff wire. Under TEE guidance, a 29-mm Evolut R prosthesis was placed at the optimal position and





Figure 2

was deployed successfully (Figure 2). After valve implantation, follow-up TEE showed mild paravalvular leak and mild to moderate AR. AR index was 24. All procedure was finished.

Live demonstration in Severance Cardiovascular Hospital, 2017 October



2018 TCT AP live demonstration case (2018.5.1) : Zero contrast TAVI

83 year-old Female

Diagnosis

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Severe AS – symptomatic
(recent syncope; CCS 1; NYHA class II)
Type 2 DM
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Old CVA

CKD (stage IV)

(Cr 2.7 mg/dL, eGFR 16 mL/min/1.73 m²)

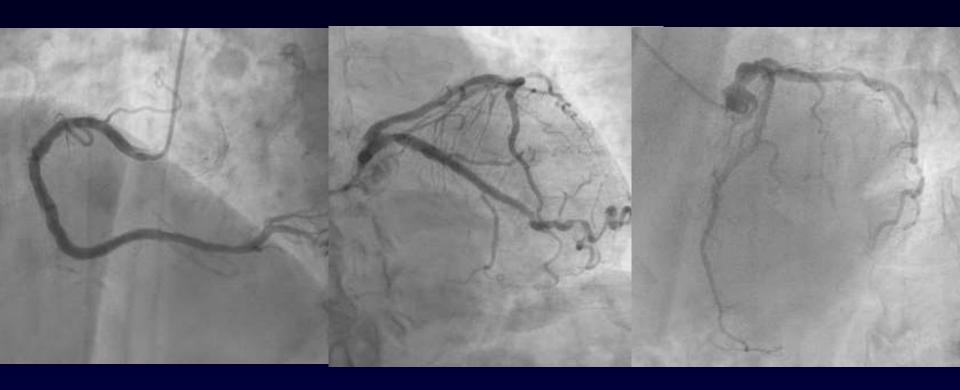
CAD (2VD); S/P PCI at LCx and LAD (2013)

Risk score

STS score = 15%



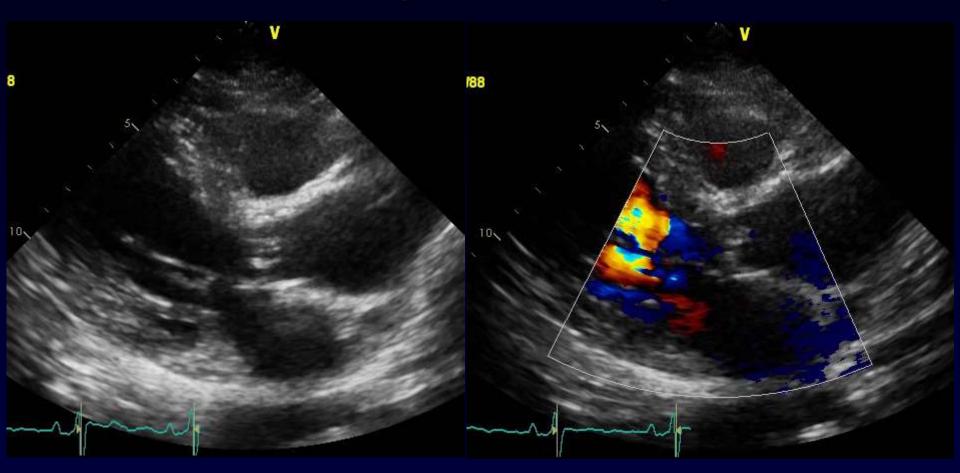
CAG – only 3 cuts taken (04 Apr 2018) for minimal contrast use



Patent previous stents (Xience 2.75*24 at LCx, Xience 2.75*28, 2.5*28 at LAD)



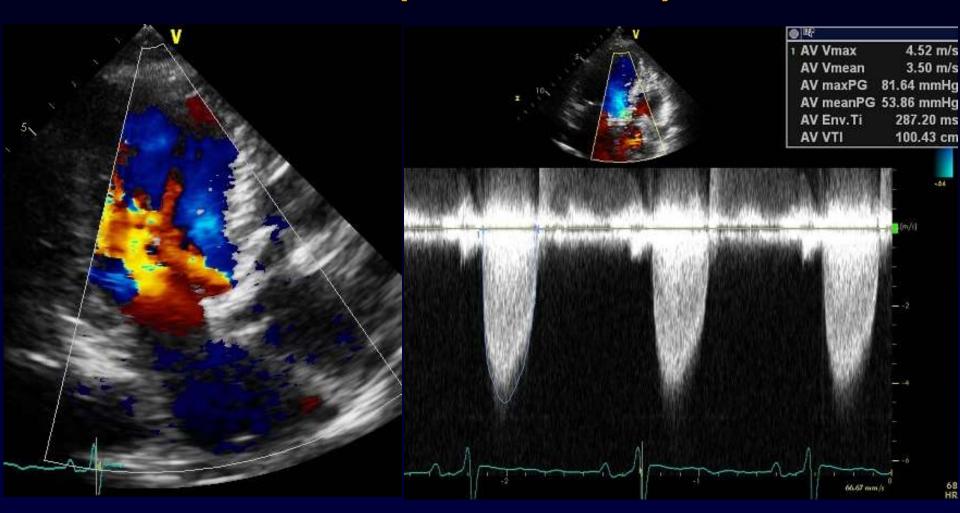
TTE (2018-04-03)



Severe AS due to degenerative AV with moderate AR (Gr. II/IV)

Normal global LV systolic function (EF: 63%)

TTE (2018-04-03)



PSPG/MSPG: 81/53 mmHg, AVA: 0.5 cm² by C.E.



3D reconstruction: TEE assessment (2018-04-04)





Valve Orifice Area

16 vps / 120 mm

7 / 28

Frame 7

20.8 mm

27.0 mm

77.5 mm

437.3 mm2

27.3 mm

33.0 mm

738.4 mm2

101.2 mm

30.5 mm 32.9 mm

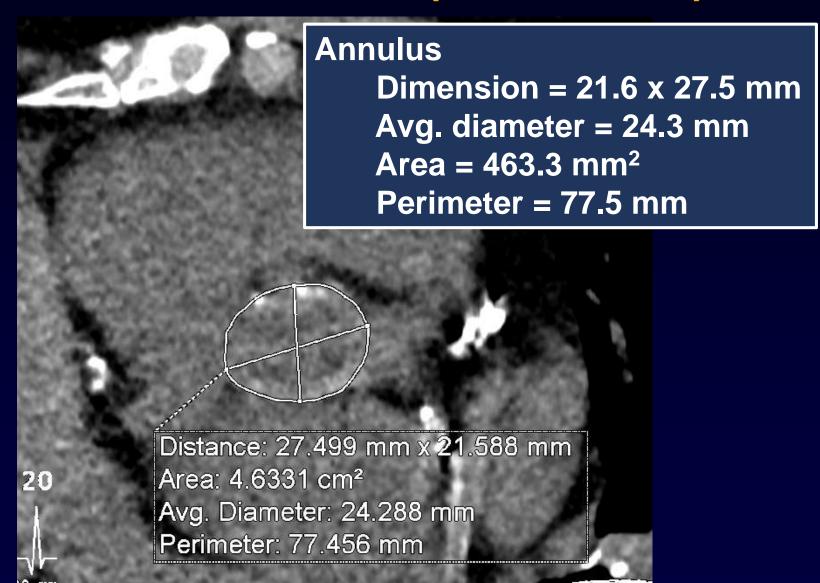
102.3 mm

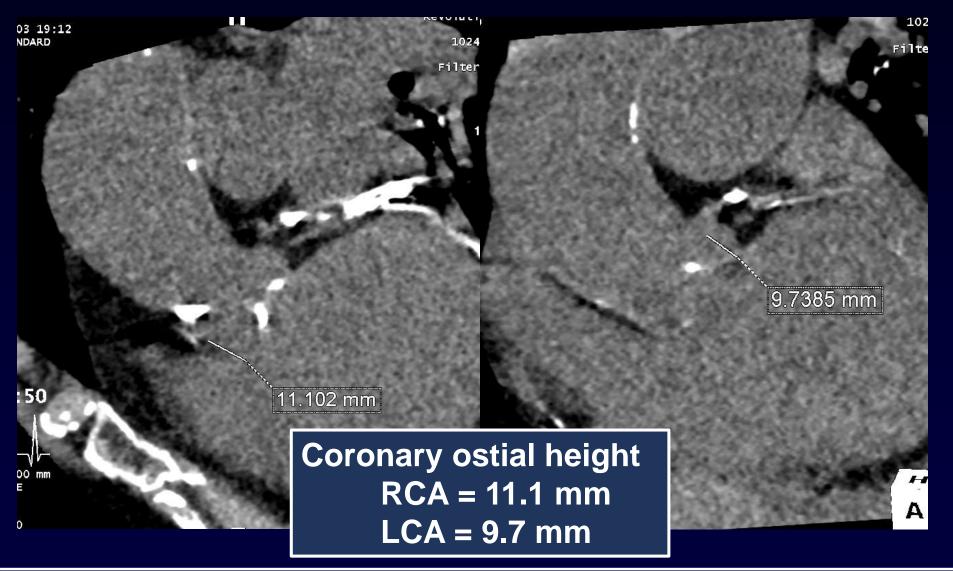
796.0 mm2

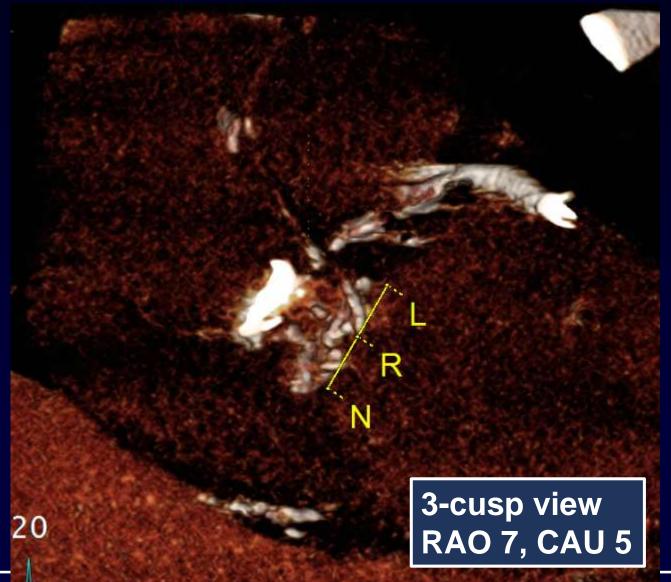
12.2 mm

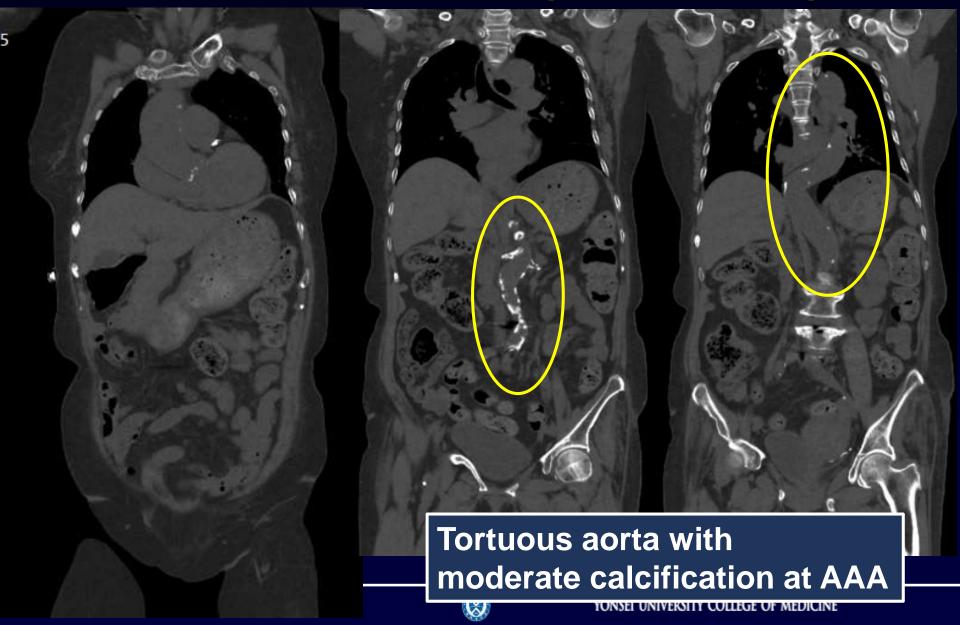
19.5 mm

46.3 mm2









Lower extremity doppler

Rt. EIA = 6.3-6.4 mm

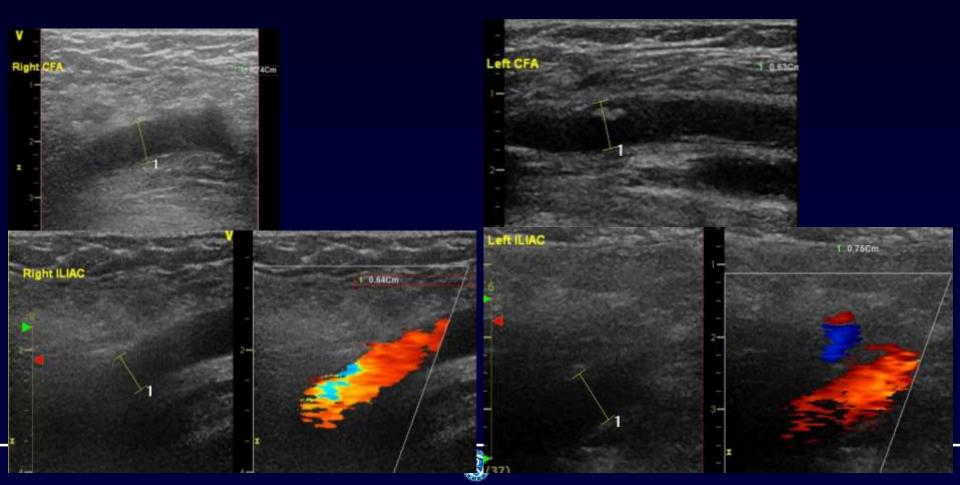
Rt. CFA = 7.4 mm

Rt. SFA = 6.0 mm

Lt. EIA = 7.1-7.5 mm

Lt. CFA = 6.3 mm

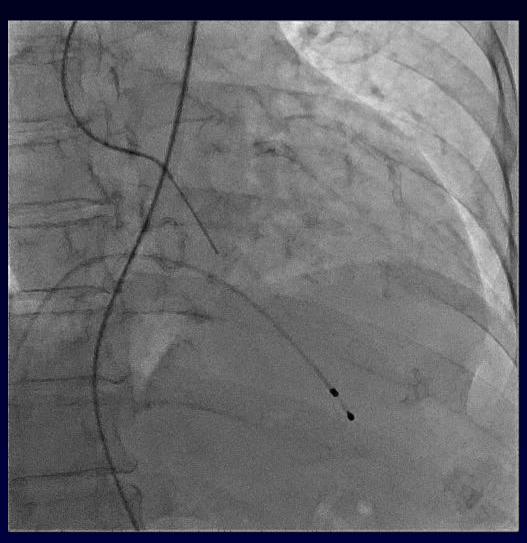
Lt. SFA = 5.7 mm



Sono-guided femoral artery puncture without contrast



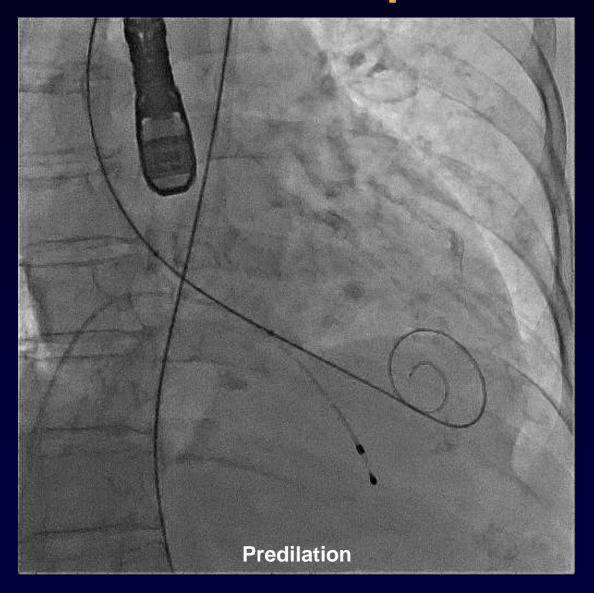
Insertion of delivery sheath (after US-guided puncture)



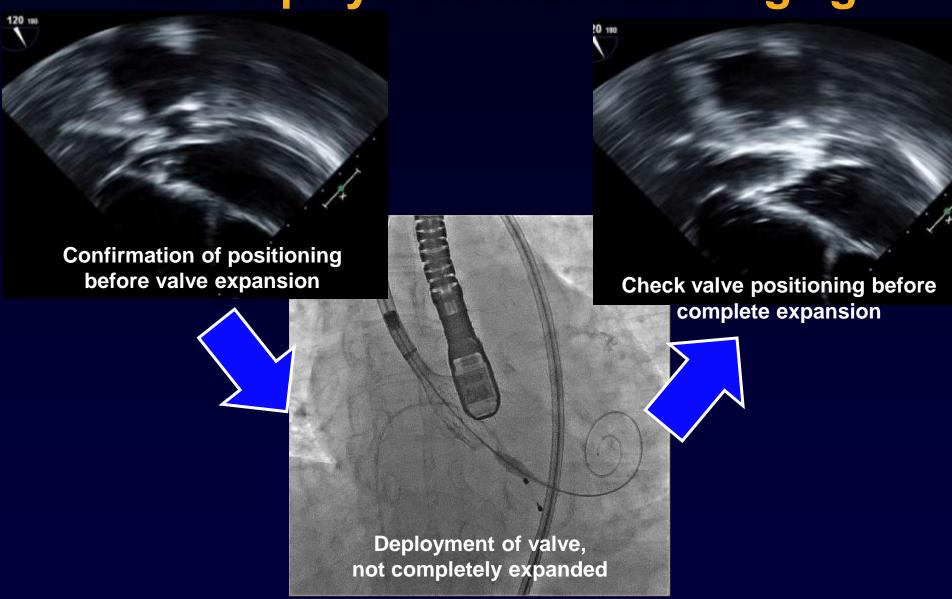
Introducing straight guidewire into LV



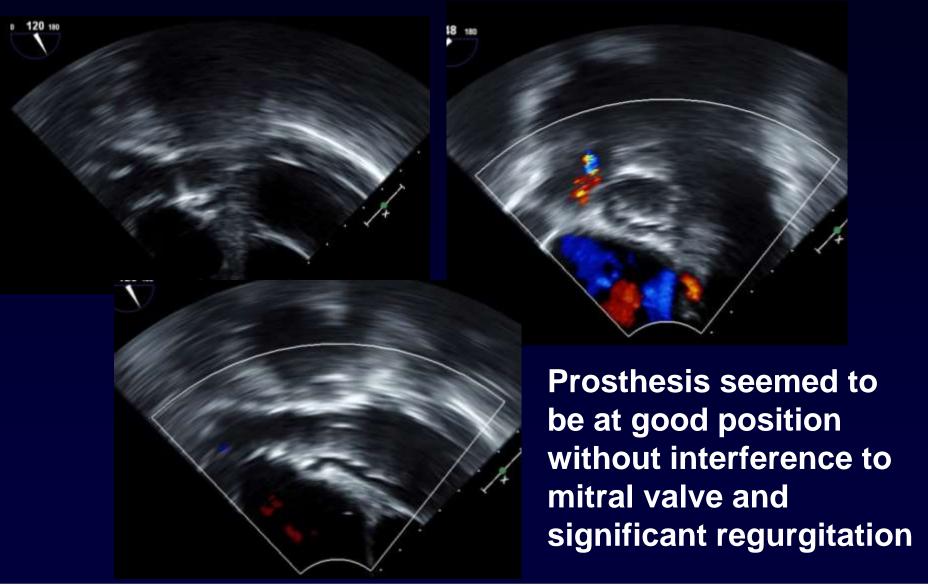
Transfemoral TAVI procedure



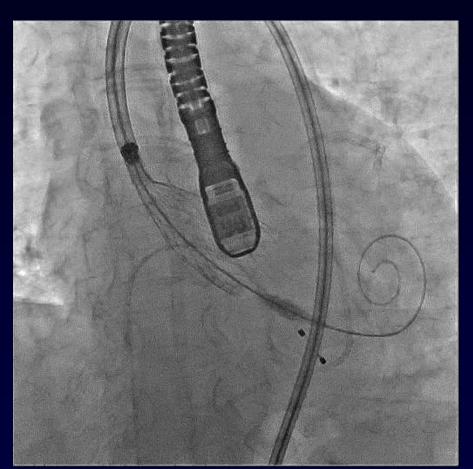
Valve deployment with TEE imaging

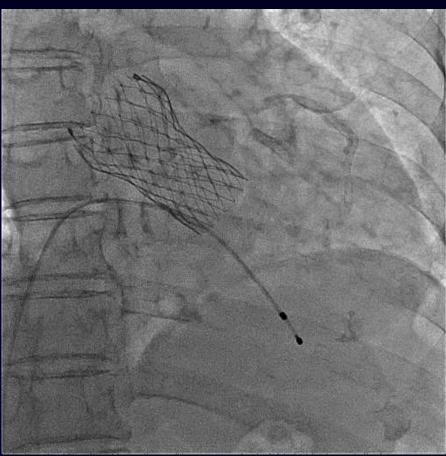


Analysis of TEE imaging



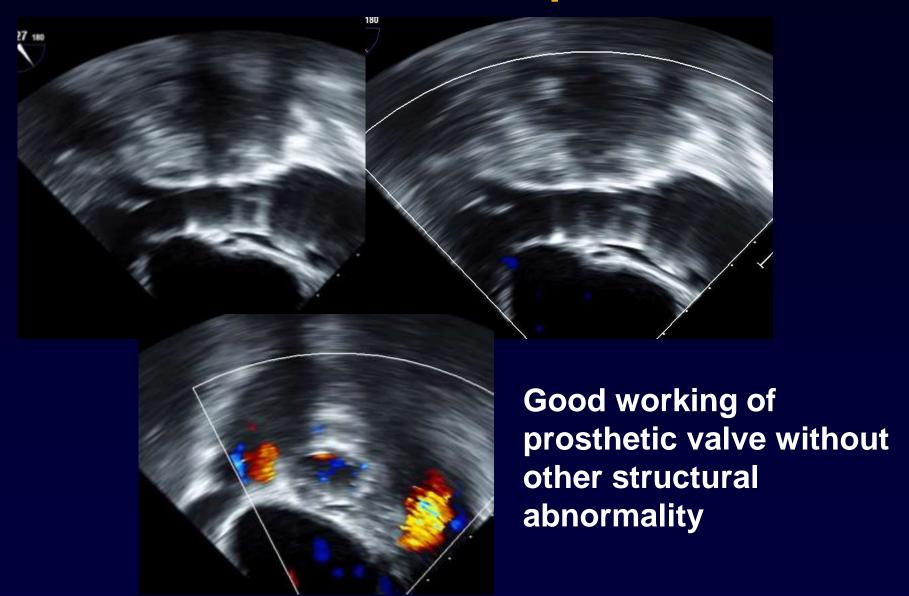
Deployment of valve



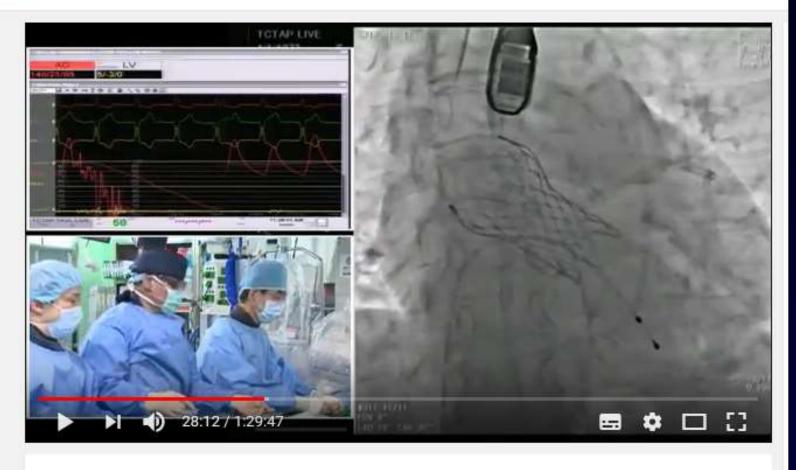


Total amount of contrast during TAVI = zero

Final evaluation of implanted valve







[TCTAP 2018] Valve Symposium - Live Case Session IV



Non-Contrast TAVI

	TAVI date	Sex	Age	STS score	serum Cr	Ccr	DM	HTN	PCI
1	2017 10 13 (2017 KSC live)	F	88	8.0%	3.12mg/dl	14ml/min/1.73 m ²	Y	Y	ND
2	2018 01 16	F	81	6.1%	1.94mg/dl	25ml/min/1.73 m ²	N	Υ	PTCA at p-mLAD, p-dLCX (2012)
3	2018 01 26	F	78	3.0%	1.69mg/dl	28ml/min/1.73 m ²	N	Y	PTCA at p-mLAD, m RCA (2012)
4	2018 02 27	F	87	17%	2.76mg/dl	16ml/min/1.73 m ²	N	N	ND
5	2018 02 27	М	76	2.7%	1.71mg/dl	35ml/min/1.73 m ²	Υ	Y	ND
6	2018 05 01 (2018 TCT AP live)	F	83	15%	2.7mg/dl	16ml/min/1.73 m ²	Υ	N	PTCA at LCx, LAD (2013)
7	2018 05 03	F	83	5.1%	1.75mg/dl	28ml/min/1.73 m ²	N	Y	ND
8	2018 07 31	F	80	11.4%	1.70mg/dl	29ml/min/1.73m ²	N	Y	ND

Poor general condition and fragile



Conclusions

Non-contrast TAVI using Evolut R should be considered in severe AS patients with poor renal function





